

REMARKS

This amendment is being re-submitted as a result of the receipt of the Notice of Non-Compliant Amendment dated February 18, 2009. Claims 13-15 were amended from "Original" to "Currently Amended" No new matter is included.

These remarks are responsive to the Office Action mailed on July 25, 2008 ("the Office Action"). The Applicants thank the Examiner for a careful and thorough examination of the above-referenced Application.

Status of the Claims

At the time of the Office Action, claims 1-15 and 55-68 were pending, with claims 1-15 and 55-68 being rejected. Claims 1, 13-15, 55, 62, and 68 are amended herein. Support for these amendments may be found throughout the Specification and within the Claims and specifically at Paragraph 0132 and Figures 43-59. No new matter is being submitted. Claims 5, 9, and 12 are canceled herein without prejudice.

Claim Objections

Claim 1 currently stands objected to for alleged informalities. Appropriate amendments are made herein. The Applicants respectfully request that these objections be withdrawn.

35 U.S.C. § 112 Rejections

Claims 1-15 and 55-68 currently stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Office Action, p. 2. "The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed

subject matter, rather than the presence or absence of literal support in the specification for the claim language.” In re *Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983).

While the Examiner objects to this claim language, the same limitation is referred to as being obvious as it would be discovered as an optimum value of a result effective variable. Office Action, p. 6. These two positions are counter to one another. The threads recited in the claim language must inherently have a depth that stops the threads within the housing. The claim language in question merely names a point within the inherent range of thread depth. The Applicants respectfully request that this rejection be withdrawn.

Claims 1-15 and 55-68 currently stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention. Office Action, p. 3. Appropriate amendments are made herein. The Applicants respectfully request that this rejection be withdrawn.

35 U.S.C. § 103 Rejections

Pending claims 1-4, 6-8, 10, 11, and 55-68 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Yuan, *et al.* (WO 01/52758), in view of Cotrel (U.S. Patent No. 5,154,719). Office Action, p. 4. Pending claims 13-14 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Yuan, *et al.*, in view of Cotrel, and further in view of Richelsoph, *et al.* (U.S. Patent Application 2003/0187442). Office Action, p. 6. Pending claim 15 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Yuan, *et al.*, in view of Cotrel and Richelsoph, *et al.*, and further in view of Bono, *et al.* (U.S. Patent No. 6,755,829). Office

Action, p. 7. In order to render a claim obvious, a combination of references must teach or suggest each and every claim limitation. The Applicants respectfully submit that the cited references, alone or combined, fail to render the present invention obvious.

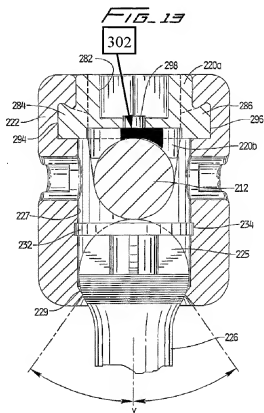
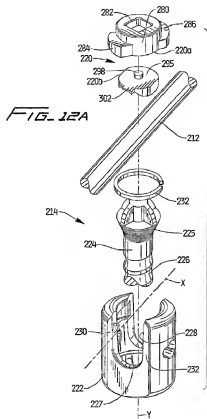
Extension Structure

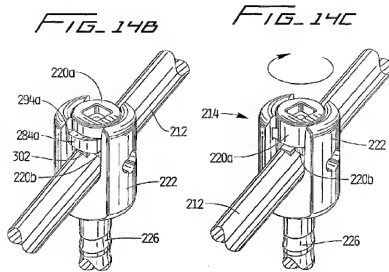
Any combination of Yuan, Cotrel, Richelsoff, or Bono fails disclose “a rod having a diameter defining a first dimension...an extension member extending radially from said lower cap,... wherein said extension member has a width that is substantially similar to said first dimension” (the “Extension Structure”), as recited by claim 1. In addition, similar structure is claimed in lines 13-14 of claim 55; lines 7-8 of claim 62; and lines 13-14 of claim 68.

The extension member is claimed to be substantially the same width as the rod diameter. An extension member of this width is capable of fitting between the claimed flanges, yet maintains alignment of the lower cap from the time it enters the housing all the way until the time it contacts the spinal rod.

In contrast, Yuan discloses an upper cap (220a), a lower cap (220b) with an extension (302), and a housing (230). However, Yuan’s extension (302) does not have a width that is *substantially similar* to a rod diameter, as recited by claim 1. As shown in Yuan’s Figures 13, 14B, and 14C, Yuan’s extension flange (302 and highlighted in figure 13) is *substantially narrower* than the rod (212) diameter. Yuan’s extension flange (302) is taught to be used as an aide “in the alignment and positioning of the lower cap portion with respect to the spinal rod.” Yuan, p. 18. However, once the lower portion (220b) is placed within the channel 228, there is no feature to ensure that the lower cap remains aligned and properly positioned from the time it enters the channel (228) to the time it

contacts the spinal rod (212). As shown in annotated Figure 13, the extension flange 302 is so narrow with respect to the width of the channel as to be ineffective in providing a constant alignment and positioning guide from the moment the cap enters the channel (228). This is also seen in Yuan's Figure 14C.





Cotrel similarly does not teach or suggest a lower cap as recited by claim 1. Instead, Cotrel teaches a small plate (11) and ring (12). Cotrel's combined plate and ring fails to disclose a lower cap as required by the claims because there is no part that extends radially and there is no part with a semi-cylindrical surface, as the Extension Structure is required to have.

Richelsoph discloses a screw and plate system, but fails to disclose any structure relating to the Extension Structure.

Bono discloses a housing and a cam component, but also fails to disclose any structure similar to the Extension Structure.

Timing Structure

The cited references also fail to disclose "threads on said upper cap and said threads in said flanges further comprise at least one start thread timed to properly engage each other when said extension is located within said channel" (the "Timing Structure"), as recited by claim 1. Similar structure is recited by in lines 21-23 of claim 55; lines 16-18 of claim 62; and lines 19-22 of claim 68.

As discussed above, Yuan discloses an upper cap (220a), a lower cap (220b) with an extension (302), and a housing (230). However, none of these components possess a structure that would obviate a Timing Structure. Yuan's structure discloses a cam, not threads. Cams cannot be cross threaded; therefore there is no need for a Timing Structure.

Cotrel teaches a housing with a plate and threaded plug. The threaded plug is used to press the plate against a rod. However, Cotrel is silent with respect to any structure related to the Timing Structure.

Richelsoph discusses U.S. Patent No. 6,139,550 to Michelson, which discloses the utilization of a cam to ensure that cam lobes stop where they should in order to engage set screws. Richelsoph, ¶ 0015. This, however, says nothing to obviate the Timing Structure.

Bono incorporates a camming component and therefore is not concerned with any Timing Structure.

For at least the reasons set forth herein, the Applicants respectfully submit that the cited references fail to render obvious independent claims 1, 55, 62, and 68, and any claim depending therefrom. Thus, the Applicants respectfully request that this rejection be withdrawn.

Conclusion

The Applicants respectfully submit that the application is in condition for allowance, and reconsideration and notice of allowance are respectfully requested. If the Examiner believes that prosecution might be advanced by discussing the application with the Applicants' counsel, in person or over the telephone, the Applicants' counsel would welcome the opportunity to do so.

Respectfully submitted,

MIDDLETON REUTLINGER

Date: January 26, 2009

/ Eric L. Killmeier /
Eric L. Killmeier
Registration No. 55,327
401 South Fourth Street
2600 Brown & Williamson Tower
Louisville, KY 40202
(502) 625-2748 direct phone
(502) 561-0442 fax
elk@middreut.com